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INVENTORS: NAREAK DOUK
NASSER RAFIEE

TITLE: LOW-PROFILE CATHETER VALVE

ATTORNEY: JAMES F. CRITTENDEN
MEDTRONIC VASCULAR, INC.
37 A CHERRY HILL DRIVE
DANVERS, MA 01923
(978) 739-3075 (direct dial)
(978) 739-3055 (fax)

LOW-PROFILE CATHETER VALVE

TECHNICAL FIELD

[001] This invention relates generally to biomedical devices that are used for treating vascular conditions. More specifically, the invention relates to a low-profile catheter valve.

BACKGROUND OF THE INVENTION

[002] Guidewires are conventionally used to guide medical instruments to a desired treatment location within a patient's vasculature. In a typical procedure, the clinician forms an access point for the guidewire by creating an opening in a peripheral blood vessel, such as the femoral artery. The highly flexible guidewire is then introduced through the opening and is advanced by the clinician through the patient's blood vessels until the guidewire extends across a vessel segment to be treated. A treatment catheter, such as a balloon catheter for a percutaneous transluminal coronary angioplasty (PTCA), may then be inserted over the guidewire and similarly advanced through vasculature until it reaches the treatment site.

[003] In certain treatment procedures, it is desirable to serially advance and withdraw a number of different treatment catheters over a single guidewire that has been placed in a particular location. Typically, a first treatment catheter is advanced over the guidewire, withdrawn, and then fully removed from the portion of the guidewire that extends out of the patient's vessel. The guidewire is then available to act as a guide for a different treatment catheter.

[004] It is sometimes advantageous to equip the distal end of a guidewire with at least one inflatable balloon, either to provide temporary occlusion of a vessel or to anchor the guidewire within a vessel. Anchoring the guidewire helps to prevent the guidewire from being displaced from its position while treatment catheters are advanced or withdrawn over the placed guidewire. An occlusion guidewire can be used as "distal protection" to prevent debris generated during vessel treatment from moving with the flowing blood to embolize distally.

[005] A permanent inflation manifold, of the type used with conventional catheters having an inflatable balloon, would prevent treatment catheters from being exchanged one for another over an occlusion guidewire. Therefore, a removable inflation manifold and a valve to maintain the balloon in the inflated state are desirable for an occlusion guidewire. U.S. Pat. No. 5,167,239 to Cohen et al. discloses one such device. However, the valve apparatus used by the Cohen device is relatively bulky, having an outer diameter in its preferred embodiment of 0.0355 inches. As can be readily appreciated, the diameter of the valve on a guidewire dictates the inner diameter and, consequently, the outer diameter of a treatment catheter introduced over the valve. Therefore, it would be desirable to provide a low-profile catheter valve that overcomes the aforementioned and other disadvantages.

SUMMARY OF THE INVENTION

[006] One aspect of the present invention is a low-profile catheter valve, comprising a catheter and a self-sealing polymer. The catheter has a central lumen and includes a plurality of longitudinal struts and longitudinal apertures interspaced around the circumference of a proximal portion of the catheter. The self-sealing polymer is disposed on at least a portion of each strut, separably sealing the struts one to another. The struts separate to allow passage of a fluid into or out of the central lumen of the catheter and reseal to prevent passage of a fluid into or out of the central lumen.

[007] Another aspect of the present invention is a system for treating a vascular condition, comprising a catheter, a self-sealing polymer, and an inflatable balloon. The catheter has a central lumen and includes a plurality of longitudinal struts and longitudinal apertures interspaced around the circumference of a proximal portion of the catheter. The self-sealing polymer is disposed on at least a portion of each strut, separably sealing the struts one to another. The inflatable balloon is operably attached to a distal portion of the catheter. The struts separate to allow inflation of the balloon through the central lumen of the catheter, reseal to maintain inflation, and separate to allow deflation of the balloon.

[008] Yet another aspect of the present invention is a method for manufacturing a low-profile catheter valve. A plurality of longitudinal apertures and longitudinal struts are formed into a proximal portion of a catheter. A self-sealing polymer is applied to at least a portion of each strut.

[009] The aforementioned and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings, which are not to scale. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] **FIG. 1** is an illustration of one embodiment of a low-profile catheter valve, in accordance with the present invention;

[0011] **FIG. 2** is a transverse cross-sectional view of the low-profile catheter valve of **FIG. 1**;

[0012] **FIG. 3** is a longitudinal cross-sectional view of an adaptor used to manipulate the low-profile catheter valve of **FIG. 1** and **FIG. 2**;

[0013] **FIG. 4** is an illustration of an alternative embodiment of a low-profile catheter valve, in accordance with the present invention;

[0014] **FIG. 5** is a transverse cross-sectional view of the low-profile catheter valve of **FIG. 4**;

[0015] **FIG. 6** is a longitudinal cross-sectional view of an alternative adaptor used to manipulate the low-profile catheter valve of **FIG. 4** and **FIG. 5**;

[0016] **FIG. 7** is an illustration of one embodiment of a system for treating a vascular condition, in accordance with the present invention;

[0017] **FIG. 8** is an illustration of another embodiment of a system for treating a vascular condition, in accordance with the present invention; and

[0018] **FIG. 9** is a flow diagram of one embodiment of a method for making a low-profile catheter valve, in accordance with the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

[0019] One aspect of the present invention is a low-profile catheter valve. One embodiment of the valve, in accordance with the present invention, is illustrated in **FIG. 1** at **100**. Valve **100** comprises catheter **110** and self-sealing polymer **120**. Catheter **110** includes a plurality of longitudinal struts **111** and longitudinal apertures **112** interspaced around the circumference of proximal portion **113**. Catheter **110** also includes central lumen **114**. Each strut has two side surfaces, first side surface **115** and second side surface **116**.

[0020] Catheter **110** may be, for example, a hollow guidewire and may include an inflatable balloon (not shown) operably attached to a distal portion of the catheter. Where catheter **110** is to be used as a guidewire during a procedure such as a conventional percutaneous transluminal coronary angioplasty (PTCA) involving femoral artery access, catheter **110** may be about centimeters to about 300 centimeters long, with a length of about 180 centimeters often being used. The outer diameter of the catheter may range from about 0.010 inches to 0.038 inches, and preferably is 0.014 inches or smaller when the catheter is to be used as a guidewire. Catheter **110** may be made of an appropriate biocompatible material such as nitinol.

[0021] Longitudinal apertures **112** may be, for example, 5 to 7 millimeters long and, in this embodiment, are preferably narrowly eye-shaped, an intersection of two circles forming two arcs with a common chord. Longitudinal struts **111** result when apertures **112** are formed into catheter **110**.

[0022] Self-sealing polymer **120** is disposed on at least one side surface of each strut. Polymer **120** separably seals first side surface **115** of each strut to second side surface **116** of the adjoining strut, thereby separably sealing struts **111** one to another and closing apertures **112**. Self-sealing polymer **120** may additionally be disposed on one or both of the inner and outer surfaces of the struts.

[0023] Self-sealing polymer **120** may be polyurethane, silicone, a suitable biocompatible polymer, or the like. Where catheter **110** is to be used as a guidewire, it may be desirable for self-sealing polymer **120** to be hydrophilic to ensure that, when valve **100** has been wetted, a second catheter may pass easily there over.

[0024] **FIG. 2**, in which like elements share like numbers with **FIG. 1**, is a transverse cross-sectional view of proximal portion **113** of valve **100**, showing longitudinal struts **111** interspaced with longitudinal apertures **112**. Self-sealing polymer **120** is shown in **FIG. 2** disposed on not only the sides of the struts, but also on the inner and outer surfaces of the struts.

[0025] While the present embodiment is illustrated in **FIG. 1** and **FIG. 2** as including four struts interspaced with four narrowly eye-shaped apertures, it will be apparent to one skilled in the art that factors such as the number, shape, size, and spacing of the longitudinal struts and longitudinal apertures may be varied as desired.

[0026] Struts **111** separate to allow passage of a fluid into or out of central lumen **114** through apertures **112** and reseal to prevent passage of the fluid into or out of central lumen **114**. In this embodiment, the proximal end of catheter **110** is sealed.

[0027] Struts **111** may separate in response to applying a mechanical force to proximal portion **113** and reseal in response to withdrawing the mechanical force. An adaptor such as that shown in **FIG. 3**, in which like elements share like numbers with **FIG. 1** and **FIG. 2**, may be used to apply and withdraw the mechanical force. Adaptor **300** may be removably mounted about proximal portion **113** as seen in **FIG. 3**. Adaptor **300** is movable between a first position in which a mechanical force is applied to proximal portion **113** and a second position in which the mechanical force is withdrawn. The adaptor is in fluid communication with a fluid delivery device through opening **340** and has at least one seal **350** that engages the circumference of catheter **110** distal to proximal portion **113**. When engaged, seal **350** establishes a fluid-tight chamber surrounding proximal portion **113**. Additional seals and gaskets may be used to ensure that the adaptor itself is fluid tight, particularly around proximal knob **360**.

[0028] **FIG. 3** shows adaptor **300** in the first position, with a mechanical force applied to proximal portion **113** using proximal knob **360**. Applying the mechanical force to proximal portion **113** axially compresses proximal portion **113** and bows struts **111** outward, separating the struts and opening apertures **112**. A fluid may now flow into adaptor **300** through opening **340** of the adaptor and then into central lumen **114** through apertures **112**. When the mechanical force is withdrawn, for example by unscrewing or pulling out proximal knob **360**, proximal portion **113** returns to an axially uncompressed condition and struts **111** reseal, preventing passage of the fluid out through the valve.

[0029] Where catheter **110** is to be used as a guidewire having an inflatable balloon at its distal end, separating struts **111** to admit a fluid permits inflation of the balloon. Resealing the struts maintains inflation of the balloon. Once struts **111** have resealed, adaptor **300** may be removed and various treatment catheters may be serially advanced and withdrawn over the guidewire. To deflate the balloon, adaptor **300** may be remounted on proximal portion **113**, and a mechanical force may be reapplied to separate struts **111** and permit the inflation fluid to pass out through apertures **112** and opening **340**.

[0030] One skilled in the art will recognize that a wide variety of adaptors may be appropriate for the present embodiment of the invention. For example, an alternative adaptor may have seals that engage the circumference of the catheter both proximal and distal to the longitudinal struts and apertures. In this example, the sealed proximal end of the catheter extends outside of the adaptor, and engaging the first and second seals establishes a fluid-tight chamber surrounding only the portion of the catheter that includes struts **111** and apertures **112**. The adaptor is movable between a first position in which a mechanical force is applied to proximal portion **113** and a second position in which the mechanical force is withdrawn. In the first position, the adaptor shortens longitudinally, axially compressing proximal portion **113**, bowing out struts **111**, and opening apertures **112**. In the second position, proximal portion **113** returns to an axially

uncompressed condition, allowing struts **111** to reseal and thereby preventing passage of the fluid out through the valve.

[0031] Another embodiment of the low-profile catheter valve, in accordance with the present invention, is illustrated in **FIG. 4** at **400**. Valve **400** comprises catheter **410** and self-sealing polymer **420**. Catheter **410** includes a plurality of longitudinal struts **411** and longitudinal apertures **412** interspaced around the circumference of proximal portion **413**. Struts **411** are radially deformed into central lumen **414** of catheter **410** such that necked-down or narrowed region **415** is formed, this narrowed region including narrowed lumen **416**. Each strut has two side surfaces, first side surface **417** and second side surface **418**.

[0032] Catheter **410** may be, for example, a hollow guidewire and may include an inflatable balloon (not shown) operably attached to a distal portion of the catheter. Where catheter **410** is to be used as a guidewire during a procedure such as a conventional percutaneous transluminal coronary angioplasty (PTCA) involving femoral artery access, catheter **410** may be about 150 centimeters to about 300 centimeters long, with a length of about 180 centimeters often being used. The outer diameter of the catheter may range from about 0.010 inches to 0.038 inches, and preferably is 0.014 inches or smaller when the catheter is to be used as a guidewire. Catheter **410** may be made of an appropriate biocompatible material such as nitinol.

[0033] Catheter **410** includes longitudinal struts **411** and longitudinal apertures **412**, which are interspaced around the circumference of proximal portion **413**. Apertures **412** may be, for example, 5 to 7 millimeters long. When struts **411** are radially deformed into central lumen **414** of catheter **410**, apertures **412** are narrowed, and narrowed region **415** is formed. Elongate hexagonal apertures are preferred for this embodiment because, when struts **411** are radially deformed into central lumen **414**, hexagonal apertures produce a narrowed region having a uniformly narrowed lumen.

[0034] **FIG. 5**, in which like elements share like numbers with **FIG. 4**, is a transverse cross-sectional view of valve **400**, showing narrowed lumen **416**, which results when struts **411** are radially deformed into central lumen **414**. Struts **411** may be heat set to maintain or "memorize" the shape of their radial deformation into central lumen **414**.

[0035] Self-sealing polymer **420** is disposed on side surfaces **417** and **418** of each longitudinal strut. First side surface **417** of each strut is separably sealed to second side surface **418** of the adjoining strut, thereby closing apertures **412** and separably sealing struts **411** one to another. Self-sealing polymer **420** is additionally disposed on an inner surface of each strut, separably sealing the inner surface of the strut to the inner surface of at least one opposing strut, thereby closing narrowed lumen **416**.

[0036] Struts **411** separate to allow passage of a fluid into or out of central lumen **414** and reseal to prevent passage of the fluid into or out of lumen **414**. In this embodiment, the proximal end of catheter **410** is not sealed, and struts **411** may separate in response to inserting a hollow needle into narrowed lumen **416** through the proximal end of catheter **410**. When the needle is inserted, struts **411** separate enough to allow passage of the needle but not enough to cause apertures **412** to gap open. The needle may be inserted completely through narrowed lumen **416** and into central lumen **414**, thereby allowing passage of a fluid through the needle and into central lumen **414**. Alternatively, the needle may be inserted only as far into narrowed lumen **416** as is necessary to cause struts **411** to separate and narrowed lumen **416** to open. In this second example, the fluid passes through the needle, through a portion of narrowed lumen **416**, and into central lumen **414**.

[0037] The polymer sealing the sides of struts **411** together may allow apertures **412** to widen, while still preventing the apertures from gapping when a needle is inserted into narrowed lumen **416**. To provide further assurance that apertures **412** will not gap open when a needle is inserted, self-sealing polymer **420** may be further disposed over the outer surface of narrowed region **415**. In this example, when struts **411** resume their narrowed configuration, self-sealing polymer **420** fills apertures **412** and narrowed lumen **416** and also forms a layer of polymer over the outer surface of narrowed region **415**.

[0038] Self-sealing polymer **420** may be polyurethane, silicone, a suitable biocompatible polymer, or the like. Where catheter **410** is to be used as a guidewire, it may be desirable for self-sealing polymer **420** to be hydrophilic to ensure that, when valve **400** has been wetted, a second catheter may pass easily there over.

[0039] As another measure to prevent gapping or to increase ease of use, an elastic material (not shown) may be coated over the outer surface of narrowed region **415**, either directly over the catheter material and any exposed self-sealing polymer or over a layer of self-sealing polymer disposed over the entire outer surface of narrowed region **415**. The elastic material may be hydrophilic to ensure that, when valve **400** has been wetted, a second catheter may pass easily there over.

[0040] Where catheter **410** is to be used as a guidewire having an inflatable balloon at its distal end, separating struts **411** to admit a fluid permits inflation of the balloon. Struts **411** reseal in response to withdrawing the needle from narrowed lumen **416**, maintaining inflation of the balloon. Once the needle has been withdrawn, various treatment catheters may be serially advanced and withdrawn over the guidewire. The needle may be reinserted to permit deflation of the balloon.

[0041] Struts **411** may also separate in response to applying a mechanical force to proximal portion **413** and reseal in response to withdrawing the mechanical force. An adaptor such as that shown in **FIG. 6**, in which like elements share like numbers with **FIG. 4** and **FIG. 5**, may be used to apply and withdraw the mechanical force.

[0042] Adaptor **600** may be removably mounted about proximal portion **413** as seen in **FIG. 6**. Adaptor **600** is movable between a first position in which a mechanical force is applied to proximal portion **413** and a second position in which the mechanical force is withdrawn. The adaptor is in fluid communication with a fluid delivery device through opening **640** and has at least one seal **650** that engages the circumference of catheter **410** distal to proximal portion **413**. When engaged, seal **650** establishes a fluid-tight chamber surrounding proximal portion **413**. Additional seals and gaskets may be used to ensure that the adaptor itself is fluid tight. Rod **665** is attached to proximal knob **660** and protrudes into adaptor **600**.

[0043] **FIG. 6** shows adaptor **600** in the first position, with a mechanical force applied to proximal portion **413** using proximal knob **660**. As seen in **FIG. 6**, when proximal knob **660** is pressed or screwed inward, rod **665** enters the proximal end of valve **400** and extends just far enough into narrowed lumen **416** to apply pressure to struts **411**, thereby separating the struts and opening not only narrowed lumen **416**, but also some or all of apertures **412**. A fluid may now flow into adaptor **600** through opening **640** and through apertures **412** into central lumen **414**. When rod **665** is withdrawn from narrowed lumen **416**, for example by unscrewing or pulling out proximal knob **660**, struts **411** reseal, closing apertures **412** and narrowed lumen **416**, and preventing fluid from passing out of the valve. Once struts **411** have resealed, adaptor **600** may be removed and various treatment catheters may be serially advanced and withdrawn over the guidewire. Adaptor **600** may be remounted to allow the fluid to be withdrawn.

[0044] While the present embodiment as illustrated in **FIGS 4** through **6** includes four struts interspaced with four hexagonal apertures, it will be apparent to one skilled in the art that factors such as the number, shape, size, and spacing of the longitudinal struts and longitudinal apertures may be varied to control the shape and size of the narrowed region.

[0045] Valves **100** and **400** are discussed above in the context of an occlusion guidewire; however, one skilled in the art will recognize that these valves may be useful in connection with other catheters into which fluids are introduced or through which fluids are withdrawn. For example, the present invention would be useful in inflating and maintaining inflation of a flow-directed catheter, which includes a low-pressure, elastomeric balloon.

[0046] Another aspect of the present invention is a system for treating a vascular condition. One embodiment of the system, in accordance with the present invention, is illustrated in **FIG. 7** at **700**. System **700** comprises catheter **710**, self-sealing polymer **720**, and inflatable balloon **730**. Catheter **710** includes a plurality of longitudinal struts **711** and longitudinal apertures **712** interspaced around the circumference of proximal portion **713**. Catheter **710** also includes a central lumen **714**. Self-sealing polymer **720** is disposed on at least a portion of each strut **711**, separably sealing the struts one to another. Struts **711** separate to allow inflation of balloon **730** through central lumen **714** of catheter **710**, reseal to maintain inflation, and separate again to allow deflation of the balloon.

[0047] Catheter **710** may be, for example, a hollow guidewire. Where catheter **710** is to be used as a guidewire for other catheters, for example in a conventional percutaneous transluminal coronary angioplasty (PTCA) procedure involving femoral artery access, catheter **710** may be about 150 centimeters to about 300 centimeters long, with a length of about 180 centimeters often being used. The outer diameter of the catheter may range from about 0.010 inches to 0.038 inches, and preferably is 0.014 inches in outer diameter or smaller when

used as a guidewire. Catheter **710** may be made of an appropriate biocompatible material such as nitinol.

[0048] Self-sealing polymer **720** may be polyurethane, silicone, a suitable biocompatible polymer, or the like. Polymer **720** is disposed on at least the side surfaces of each strut **711**. Polymer **720** separably seals a first side surface of each strut to a second side surface of the adjoining strut, thereby separably sealing the struts one to another and closing the intervening apertures **712**, which may be narrowly eye-shaped. Self-sealing polymer **720** may additionally be disposed on one or both of the inner and outer surfaces of the struts.

[0049] Self-sealing polymer **720** may be polyurethane, silicone, a suitable biocompatible polymer, or the like. Where catheter **710** is to be used as a guidewire, it may be desirable for polymer **720** to be hydrophilic to ensure that, when polymer **720** has been wetted, a second catheter may pass easily there over.

[0050] In the present embodiment as seen in **FIG. 7**, the proximal end of catheter **710** is sealed. The system as depicted may be operated using an adaptor such as that shown in **FIG. 3**. The adaptor may be removably mounted on proximal portion **713** of catheter **710**. The adaptor has a seal to engage the circumference of catheter **710** distal to proximal portion **713**. Engaging the seal establishes a fluid-tight chamber surrounding proximal portion **713**. The adaptor is movable between a first position in which a mechanical force is applied to proximal portion **713** and a second position in which the mechanical force is withdrawn. Applying the mechanical force to proximal portion **713** bows struts **711** outward, separating the struts and opening apertures **712**. The adaptor is in fluid communication with a fluid delivery device, and a fluid can now flow into the adaptor and through apertures **712** and central lumen **714** to inflate balloon **730**. When the mechanical force is withdrawn, struts **711** reseal to maintain inflation of the balloon. Once the struts have resealed, the adaptor may be removed and

treatment catheters may be serially advanced and withdrawn over the guidewire. To deflate the balloon, the adaptor may be remounted and the force reapplied to separate struts **711** and allow the fluid to pass out through apertures **712**.

[0051] Another adaptor for use with the present invention may have seals that engage the circumference of the catheter both proximal and distal to the longitudinal struts and apertures. Using this adaptor, the sealed proximal end of catheter **710** extends outside of the adaptor, and the first and second seals establish a fluid-tight chamber surrounding only the portion of the catheter that includes struts **711** and apertures **712**. The adaptor is movable between a first position in which a mechanical force is applied to proximal portion **713** and a second position in which the mechanical force is withdrawn. In the first position, the adaptor shortens longitudinally, thereby applying a mechanical force to axially compress proximal portion **713**, bowing struts **711** outward, and opening apertures **712**. In the second position, proximal portion **713** returns to an axially uncompressed configuration, allowing struts **711** to reseal and apertures **712** to close, thus preventing flow of a inflation fluid into or out of system **700**.

[0052] Inflatable balloon **730** is operably attached to a distal portion of catheter **710**. Inflatable balloon **730** may be made of a suitable material such as thermoplastic polyurethane (TPU) resins, styrene-ethylene-butadiene-styrene (SEBS), PEBAX, or the like.

[0053] Another embodiment of a system for treating a vascular condition, in accordance with the present invention, is illustrated in **FIG. 8** at **800**. System **800** comprises catheter **810**, self-sealing polymer **820**, and inflatable balloon **830**. Catheter **810** includes a plurality of longitudinal struts **811** and longitudinal apertures **812** interspaced around the circumference of proximal portion **813**. Struts **811** are radially deformed into central lumen **814** of catheter **810** such that narrowed region **815** is formed in the catheter, narrowed region **415** including narrowed lumen **816**.

[0054] Self-sealing polymer **820** may be polyurethane, silicone, a suitable biocompatible polymer, or the like. Polymer **820** is disposed on the side surfaces of each strut **811**. Polymer **820** separably seals a first side surface of each strut to a second side surface of the adjoining strut, thereby separably sealing the struts one to another and closing the intervening apertures **812**, which are preferably elongate hexagons in this embodiment. Self-sealing polymer **820** is additionally disposed on an inner surface of each strut, separably sealing the inner surface of the strut to the inner surface of at least one opposing strut, thereby closing narrowed lumen **816**.

[0055] Struts **811** separate to allow inflation of balloon **830** through central lumen **814** of catheter **810**, reseal to maintain inflation, and separate again to allow deflation of the balloon. In this embodiment, the proximal end of catheter **810** is not sealed, and struts **811** may separate in response to inserting a hollow needle into narrowed lumen **816** through the proximal end of catheter **810**. When the needle is inserted, struts **811** separate enough to allow passage of the needle but not enough to cause apertures **812** to gap open. The needle may be inserted completely through narrowed lumen **816** and into central lumen **814**, thereby allowing passage of a fluid through the needle and into central lumen **814**. Alternatively, the needle may be inserted only as far into narrowed lumen **816** as is necessary to cause struts **811** to separate and narrowed lumen **816** to open. In this second example, the fluid passes through the needle, through a portion of narrowed lumen **816**, and into central lumen **814**.

[0056] The polymer sealing the sides of struts **811** together may allow apertures **812** to widen, while still preventing the apertures from gapping when a needle is inserted into narrowed lumen **816**. To provide further assurance that apertures **812** will not gap open when a needle is inserted, self-sealing polymer **820** may be further disposed over the outer surface of narrowed region **815**. In this example, when struts **811** resume their narrowed configuration, self-sealing polymer **820** fills apertures **812** and narrowed lumen **816** and also forms a layer of polymer over the outer surface of narrowed region **815**.

[0057] As another measure to prevent gapping or to increase ease of use, an elastic material (not shown) may be coated over the outer surface of narrowed region **815**, either directly over the catheter material and any exposed self-sealing polymer or over a layer of self-sealing polymer disposed over the entire outer surface of narrowed region **815**. The elastic material may be hydrophilic to ensure that, when the elastic material has been wetted, a second catheter can pass easily there over.

[0058] Struts **811** may also separate in response to applying a mechanical force to proximal portion **813** and reseal in response to withdrawing the mechanical force. An adaptor such as that shown in **FIG. 6** may be used to apply and withdraw the mechanical force.

[0059] The adaptor may be removably mounted on proximal portion **813** of catheter **810**. The adaptor has a seal to engage the circumference of catheter **810** distal to proximal portion **813**. Engaging the seal establishes a fluid-tight chamber surrounding proximal portion **813**. The adaptor is movable between a first position in which a mechanical force is applied to proximal portion **813** and a second position in which the mechanical force is withdrawn. Applying the mechanical force to proximal portion **813** inserts a rod into narrowed lumen **816**, separating the struts and opening apertures **812**. The adaptor is in fluid

communication with a fluid delivery device, and a fluid can now flow into the adaptor and through apertures **812** and central lumen **814** to inflate balloon **830**. When the mechanical force is withdrawn, thereby removing the rod from narrowed lumen **816**, struts **811** reseal to maintain inflation of the balloon. Once the struts have resealed, the adaptor may be removed and treatment catheters may be serially advanced and withdrawn over the guidewire. To deflate the balloon, the adaptor may be remounted and the mechanical force reapplied to separate struts **811** and allow the fluid to pass out through apertures **812**.

[0060] Inflatable balloon **830** is operably attached to a distal portion of catheter **810**. Inflatable balloon **830** may be made of a suitable material such as thermoplastic polyurethane (TPU) resins, styrene-ethylene-butadiene-styrene (SEBS), PEBAX, or the like.

[0061] Although described above in the context of an occlusion guidewire, systems **700** and **800** may be readily adapted to a wide variety of balloon catheters, including those having additional functionalities, structures, or intended uses.

[0062] Yet another aspect of the present invention is a method for manufacturing a low-profile catheter valve. **FIG. 9** shows a flow diagram of one embodiment in accordance with the present invention at **900**.

[0063] A plurality of longitudinal apertures and longitudinal struts are formed into a proximal portion of a catheter (**Block 910**). The longitudinal apertures may be formed by, for example, laser cutting or chemical etching the apertures through the wall of the catheter. The longitudinal struts are formed when the longitudinal apertures are cut or etched into the catheter and are, therefore, interspaced with the longitudinal apertures.

[0064] The longitudinal struts may be deformed into a central lumen of the catheter such that a narrowed region is formed in the catheter, the narrowed region having a narrowed lumen (**Block 920**). This may be accomplished by, for example, placing a removable mandrel within the portion of the catheter containing the longitudinal struts, the mandrel having an outer diameter equal to the desired inner diameter of the narrowed lumen. A radial compressive force may then be applied simultaneously to all of the struts. Radially compressing the longitudinal struts narrows the longitudinal apertures, thus forming a narrowed region in the catheter, the narrowed region having a narrowed lumen. The narrowed region may then be heat-treated, for example in an oven or a heat set block, to maintain or set the shape memory of the radial compression of the longitudinal struts into the central lumen of the catheter (**Block 930**).

[0065] A self-sealing polymer is applied to at least a portion of each longitudinal strut (**Block 940**). This may be accomplished by, for example, bowing the longitudinal struts into an outwardly extended position and coating the polymer onto at least a portion of each strut. The self-sealing polymer may be polyurethane, silicone, a suitable biocompatible polymer, or the like.

[0066] An elastic coating may be applied over an outer surface of the catheter's narrowed region using a suitable method such as spraying or painting (**Block 950**). The coating material may be applied directly onto the outer surfaces of the longitudinal struts and any self-sealing polymer exposed in the longitudinal apertures, or it may be applied over a layer of self-sealing polymer disposed over the entire outer surface of the narrowed region.

[0067] It will be apparent to one skilled in the art that a low-profile catheter valve may be manufactured using just two of the above steps: forming a plurality of longitudinal apertures and longitudinal struts into a proximal portion of a catheter; and applying a self-sealing polymer to at least a portion of each strut, that portion being the side surfaces of the longitudinal struts.

[0068] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes and modifications that come within the meaning and range of equivalents are intended to be embraced therein.